

## **REMARKS**

Claims 2-6, 8, 9, 11, 13, 14, 16-19, 21, 22, 24, 31-33, 35, 36 and 73-76 remain in this application.

**The Rejection of Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73 were rejected under 35 USC §103(a) as Unpatentable Over Cherukuri et al. (EP 0,458,751) in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) Should be Withdrawn**

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73 were rejected under 35 USC §103(a) as unpatentable over Cherukuri et al. (EP 0,458,751) in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999). Applicants respectfully disagree for the reasons that follow.

The current claims relate to a texture masked particle comprising a core containing an active ingredient and a first and second coating layer. As recited in claim 8, the first coating layer is comprised of a taste masking agent that substantially covers the core, wherein said taste masking agent is comprised of an insoluble film forming polymer; and a second coating layer on the surface of the first coating layer, the second coating layer comprised of (i) a water soluble and/or water swellable film forming polymer and (ii) an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof. According to the Office Action,

“Cherukuri et al teach a delivery system for a cyclic amino acid compound which offers reduced bitterness and improved mouthfeel with desired high temperature stability. . . . Cherukuri et al. does not teach the second coating layer is comprises of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol or the claimed ratios. It is for this reason Kanai et al. and Uchida et al. are added as secondary references.”

See pages 4-5 of the Office Action. In addressing the teachings of Kanai et al. and Uchida et al., the Office Action states:

Kanai et al. teach the resulting tablets were coated with a film coating agent consisting of hydroxypropyl methyl cellulose . . . , polyethylene glycol 6000 . . . , castor oil and ethanol, giving film coated tablets of the composition . . . . Uchida et al. further teach the tablets thus obtained were coated with a film comprising hydroxymethyl cellulose . . . , polyethylene glycol 6000 . . . , castor oil and methanol to prepare film-coated tablets. . . . Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element on the invention has been fairly suggested by the cited reference. (emphasis added).

See pages 5-7 of the Office Action.

Applicants again respectfully disagree. As discussed above, the current claims relate to coated particles, not to a coated tablet. As emphasized above, both Kanai et al. Uchida et al. teach the use of the recited coatings in tablet coatings, not particle coatings as recited in the pending claims.

As discussed in the Background of the Invention section, Applicants explain the need for texture of the drug-containing particles, especially in chewable tablets where the tablet coating is broken. Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed. Neither, Kanai et al. and Uchida et al. disclose or suggest the current claimed coated particles or methods of manufacturing coated particles.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

**The Rejection of Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-76 were rejected under 35 USC §103(a) as Unpatentable Over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) Should be Withdrawn**

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73 were rejected under 35 USC §103(a) as unpatentable over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999). Applicants respectfully disagree for the reasons that follow. According to the Office Action,

CA 2,068,366 teaches a taste-masked free-slowing powder including microcapsules having a particle size of 300 microns or less that includes a core element including at least one pharmaceutically active ingredient . . . . CA 2,068,366 does not teach the second coating layer is comprises of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol or the claimed ratios. It is for this reason Kanai et al. and Uchida et al. are added as secondary references. . . . Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element on the invention has been fairly suggested by the cited reference.

See Pages 7-11 of the Office Action.

Applicants again respectfully disagree. As discussed in the above rejection, the current claims relate to coated particles, not to a coated tablet. Also as discussed above, both Kanai et al. Uchida et al. teach the use of the recited coatings in tablet coatings, not particle coatings as recited in the pending claims. Neither, Kanai et al. and Uchida et al. disclose the current claimed coated particles or methods of manufacturing coated particles.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

### **Conclusion**

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the presently presented claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is

requested to telephone the undersigned Attorney at the below-listed number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP0231USNP/WEM.

Respectfully submitted,

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